Section III (Remarks)

Summary of Amendments To The Specification

Replacement paragraph [0030] eliminates a typographical error present in the original paragraph [0030]; namely, the fragment "are materials suitably used for this purpose" has been eliminated from the end of the paragraph.

Summary of Amendments To The Claims

Claims 1 and 29 have been amended to add the limitation "wherein the second balloon is coated with a hemostatic agent adapted to moderate or reduce hemorrhage of a body cavity into which said balloon catheter is inserted," similar to the language of former (now cancelled) dependent claim 15. Support for the added limitation is provided in the original disclosure, for example, in paragraph number [0030]. Claim 29 has been further amended to replace "a" with "an" preceding the term "inflatable."

Claim 43 has been amended to substitute the term "insertable" for the term "inserted."

Claim 50 has been rewritten in independent form and amended to substitute the express language of former claim 1 in lieu of the phrase "as in claim 1."

Claim 52 has been added. Support for the added claim is provided in the original disclosure, for example, in paragraph number [0030].

Claim 15 has been cancelled in view of the amendment to claim 1.

Elected claims 1-15, 29-39, 43-44, 50, and 52 are now pending as a result of the amendments to the claims, with claims 16-28, 40-42, 45-49, and 51 having been previously withdrawn.

No new matter within the meaning of 35 U.S.C. 132 has been added by the foregoing amendments.

Claim Rejections

In the December 15, 2005 Office Action, claims 1-4, 1-9, 11-28, 30-34 and 38 were rejected on various grounds over various references and/or combinations thereof, including:

- a rejection of claims 1-4, 6, 9, 12-15, 29-32, 34-35, and 37 under 35 USC §102(b), as being anticipated by Stambaugh (U.S. Patent No. 6,136,011);
- a rejection of claims 1-5, 8, 10, 12-14, 29-33, 36, and 38 under 35 USC §102(b), as being anticipated by Fogarty (U.S. Patent No. 4,338,942);
- a rejection of claims 1-4, 6-8, 12-14, 29-32, 34-36, 43-44, and 50 under 35 USC §102(b), as being anticipated by Diederich (U.S. Patent No. 6,746,465); and
- a rejection of claims 11 and 39 under 35 USC §103(a), as being unpatentable over Stambaugh, Fogarty, or Diederich in view of Wang (U.S. Patent No.5,512,051).

These rejections are traversed, as detailed below.

Law relating to the rejections under 35 USC § 102(b), followed by a discussion of the disclosures of the cited art and traversal of the § 102(b) rejections, is provided below. Thereafter, law relating to the rejections under 35 USC § 103(a), followed by a discussion of the disclosures of the cited art and traversal of the § 103(a) rejections, is provided.

A. Rejections Under 35 USC § 102(b)

1. Law Regarding Rejections Under 35 USC § 102(b)

In order for a §102(b) rejection of claims to be legally proper, the single cited reference must meet the criteria stated in MPEP §706.02, i.e., the cited reference:

> **"must teach every aspect of the claimed invention either explicitly or implicitly. Any feature not directly taught must be inherently present."** (MPEP §706.02, Rejection on Prior Art [R-1]).

The governing law of CAFC decisions is consistent with such MPEP standard:

> "Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, "**anticipation requires** the presence in a single prior art reference **disclosure of each and every element of the claimed invention, arranged as in the claim**." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, "[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Rejection of claims 1-4, 6, 9, 12-15, 29-32, 34-35, and 37 under 35 USC §102(b) as anticipated by Stambaugh and traversal thereof

Stambaugh discloses a double balloon intravascular stent delivery device having multiple non-concentric lumens, one long outer balloon, and one short inner balloon. The outer balloon may serve as a safety device in case of rupture of the inner balloon to capture any expansion fluid that is lost as a result (col. 2, lines 57-67). The two balloons may be inflated and deflated independently. The invention provides for the center section of a stent to be expanded before the ends of the stent to ensure that the structure undergoes substantially its entire longitudinal contraction before the ends make contact with the vessel walls (col. 2, lines 28-33). This facilitates uniform deployment of the stent while reducing the trauma that the ends of the stent can inflict on the lumen walls (col. 2, lines 23-26).

Claims 1-4, 6, 9, 12-14, 29-32, 34-35, and 37 each require, *inter alia*, that "**the second balloon is coated with a hemostatic material adapted to moderate or reduce hemorrhage of a body cavity into which said balloon catheter is inserted.**" Nothing in Stambaugh teaches or suggests this limitation. The rejection of claim 15 has been rendered moot by cancellation of that claim.

Since "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (*Lindemann, supra)*, and Stambaugh fails to disclose each and every element of claims 1-4, 6, 9, 12-14, 29-32, 34-35, and 37, withdrawal of the rejection of such claims under 35 USC § 102(b) is respectfully requested.

3. Rejection of claims 1-5, 8, 10, 12-14, 29-33, 36, and 38 under 35 USC §102(b) as anticipated by Fogarty and traversal thereof

Fogarty discloses a concentric double balloon and concentric double lumen catheter assembly useful for treating occlusions (e.g., occluded arteries or veins). An outer balloon encases an inner balloon that is twisted for retraction while the outer balloon is inflated. Subsequent deflation of the outer balloon serves to provide a smooth buffering surface to prevent damage to the wall of the adjacent artery or vein as the catheter is moved past the same.

Claims 1-5, 8, 10, 12-14, 29-33, 36, and 38 each require, *inter alia*, that "**the second balloon is coated with a hemostatic material adapted to moderate or reduce hemorrhage of a body cavity into which said balloon catheter is inserted.**" Nothing in Stambaugh teaches or suggests this limitation.

Since "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (*Lindemann, supra)*, and Fogarty fails to disclose each and every element of claims1-5, 8, 10, 12-14, 29-33, 36, and 38, withdrawal of the rejection of such claims under 35 USC § 102(b) is respectfully requested.

4. Rejection of claims 1-4, 6-8, 12-14, 29-32, 34-36, 43-44, and 50 under 35 USC §102(b) as anticipated by Diederich and traversal thereof

Diederich discloses a double balloon catheter device with multiple non-concentric lumens for shielding and/or positioning sensitive non-target tissues and organs during treatment (e.g., thermal, acoustic, or radiation treatment) of a target tissue to reduce physiological effects of such exposure. Gases and/or liquids may be supplied or cycled through the balloon(s) and sensors may be provided to act as a thermal sink (e.g., to avoid hyperthermia in sensitive tissues), a thermal source, a radiation absorber, a radiation transmitter, an acoustic conductor, or an acoustic

insulator. Use of the catheter device is disclosed in conjunction with prostate treatment, treatment of gynecological diseases (including menorrhagia, uterine cancer, cervical cancer, and uterine fibroids). A balloon "may also be configured to inflate to shapes that are lobed, spoon-shaped, generally planar, symmetrical, or any desired shape that will displace tissues or organs to the preferred positions, and provide treatment modification, protection, or thermal control." Col. 7, lines 49-53. No mention is made of postpartum therapy, hemorrhage, or bleeding, or any strategies to control bleeding.

Claims 1-4, 6-8, 12-14, 29-32, 34-36, 43-44 each require, *inter alia*, that **"the second balloon is coated with a hemostatic material adapted to moderate or reduce hemorrhage of a body cavity into which said balloon catheter is inserted."** Nothing in Diederich teaches or suggests this limitation. Accordingly, since Diederich fails to teach or suggest all of the limitations of claims 1-4, 6-8, 12-14, 29-32, 34-36, 43-44, such claims cannot be anticipated, and withdrawal of the rejection of these claims under 35 USC § 102(b) is respectfully requested.

Claim 50 is directed to "[a] method for controlling post-partum hemorrhage" and requires, *inter alia*:

> **"inserting [a] balloon catheter apparatus into at least one of an internal uterine wall area and a vaginal wall area; and inflating the first balloon with a gaseous medium so as to apply a substantially even pressure over the at least one wall area for reducing or eliminating bleeding therein."**

Diederich fails to teach or suggest any method for controlling hemorrhage; instead, Diederich teaches the use of a balloon catheter device for **positioning and/or shielding** non-target tissues and organs during treatment (e.g., thermal, acoustic, or radiation treatment) of a target tissue. None of these treatment methods contemplate laceration or abrasion of tissues that would give rise to a bleeding problem. Clearly, inflating a balloon catheter device within a uterus or vagina to apply pressure to a wall thereof (e.g., to control hemorrhage) will not serve to "reposition an organ," since the position of these uterine and vaginal structures are fixed. Diederich teaches that the device may be used interstitially as well as laproscopically (e.g., involving use of a fiber optic for visual examination) or endoscopically (e.g., for visualizing the interior of a hollow organ). See Diederich, col. 6, lines 50-52. While Diederich does mention interstitial, laproscopic, or endoscopic use of a catheter device for procedures in the uterus/cervix (col. 6, lines 50-52), nothing in Diederich suggests that the catheter device is useful for

"apply[ing] substantially even pressure over the at least one wall area for reducing or eliminating bleeding therein" as required by claim 50. Accordingly, since Diederich fails to teach or suggest all of the limitations of claim 50, the claim cannot be anticipated, and withdrawal of the rejection of claim 50 under 35 USC § 102(b) is respectfully requested.

B. Rejections Under 35 USC § 103(a)

1. Law Regarding Rejections Under 35 USC § 103(a)

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. M.P.E.P. § 2143.

Furthermore, a basic consideration, which applies to all obviousness rejections, is that references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. MPEP 2141.02.

2. Rejection of claims 11 and 39 under 35 USC §103(a) as unpatentable over Stambaugh, Fogarty, or Diederich in view of Wang, and traversal thereof

Stambaugh, Fogarty, and Diederich have been discussed herein. Wang discloses a slip-layered multi-balloon catheter device with multiple non-concentric lumens, the device being adapted for insertion into a bodily conduit such as an artery. Between the balloon layers is disposed a low-friction substance to cause the layers to readily slide with respect to one another as the balloon is inflated and deflated.

Claims 11 and 39 each require, *inter alia*, that **"the second balloon is coated with a hemostatic material adapted to moderate or reduce hemorrhage of a body cavity into which said balloon catheter is inserted."** Nothing in any of Stambaugh, Fogarty, Diederich, or Wang,

whether alone or in combination, teaches or fairly suggests this limitation. Since the cited references fail to teach all of the limitations of the claims as required by M.P.E.P. § 2143.03, no prima facie case of obviousness has been established, and the rejection of claims 11 and 39 under 35 USC §103(a) cannot stand. Accordingly, withdrawal of the rejection of claims 11 and 39 under 35 USC §103(a) is respectfully requested.

New Claim

Claim 52, which is newly presented and depends from claim 50, includes the limitation that "the second balloon is coated with a hemostatic material adapted to moderate or reduce hemorrhage of the at least one wall area." The novelty and non-obviousness of this subject matter has been discussed hereinabove.

Fee Payable For Added Claim

By the present Amendment, Applicants have added 1 independent claim (i.e., by rewriting claim 50 in independent form). The total number of claims has not changed despite the addition of one claim (claim 52) because one claim (claim 15) has also been cancelled. The fee for the addition of one independent claim [calculated as (1 x $100 =) $100 under 37 CFR 1.16(h)] is hereby authorized to be charged to the credit card specified in the Credit Card Payment Form PTO-2038 enclosed herewith. Any deficiency is hereby authorized to be charged to Deposit Account No. 08-3284 to effect entry of this Response.

CONCLUSION

Claims 1-15, 29-39, 43-44, 50, and 52 are fully distinguished over the cited references, and are in form and condition for allowance. Issuance of a Notice of Allowance for the application is therefore requested. If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application may be allowed and passed to issue at an early date.

Respectfully submitted,

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